

Applicants: Douglas J. M. Allen et al.  
Serial No.: 10/716,098  
Filed : November 17, 2003  
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**Remarks**

Claims 12-25 were pending in the subject application. By this amendment, applicants have amended claims 16, 23 and 25, canceled claims 14 and 15 without disclaimer or prejudice, and added new claim 26. Accordingly, claims 12-13 and 16-26 will be pending and under examination upon entry of this response.

**Rejection under 35 U.S.C. §112, second paragraph**

In the October 10, 2006 Office Action, the Examiner rejected claims 23 and 25 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner alleged that claim 23 recites the limitation of "hyperproliferative disorder" which has indefinite metes and bounds, and is not defined in the specification. The Examiner also alleged that claim 25 recites the agent of "cell-cycle inhibitors" which is broad in limitation, and it also recites the agent of "mitotic inhibitors" which is a narrow limitation. The Examiner rejected claim 25 for allegedly not clearly setting forth the metes and bounds of the patent protection desired. The Examiner also stated that the limitation of "biological response modifiers" has indefinite metes and bounds and further alleged that the specification does not define what constitute a biological response modifier.

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*Applicants' Response:*

Claim 23

Applicants respectfully submit that the term "hyperproliferative disorder" is a well understood term by those of skill in the art. More importantly, the term is defined in the subject application. Specifically, the hyperproliferative disorders that the present invention is useful in preventing are described on page 5, line 18, to page 6, line 7 of the subject application.

Applicants have also amended claim 23 to depend upon claim 16 instead of claim 12.

Claim 25

To advance prosecution of the subject application but without conceding the correctness of the Examiner's position, applicants have amended claim 25 to remove the term "biological response modifiers". Applicants have further amended claim 25 to remove the term "mitotic inhibitor" and introduced new claim 26 directed to the use of a "mitotic inhibitor".

Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

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**DOUBLE PATENTING**

On page 3 of the October 10, 2006 Official Action, the Examiner rejected claims 11-25 under the doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1 and 6-9 of U.S. Patent No. 6,706,721. The Examiner alleged that the conflicting claims are not patently distinct from each other.

In response, Applicants attach hereto as **Exhibit 1** a Terminal Disclaimer which disclaims the terminal portion of the statutory term of any patent granted on the subject application which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §154 to §156 and §173 of commonly assigned U.S. Patent No. 6,706,721. Accordingly, the double patenting rejection is moot with respect to U.S. Patent No. 6,706,721.

Under 37 C.F.R. §1.321(b), a terminal disclaimer must be accompanied by the fee set forth in 37 C.F.R. §1.20(d). Under 37 C.F.R. §1.20(d), the fee for filing a terminal disclaimer is ONE HUNDRED THIRTY DOLLARS (\$130.00) and a check including this amount is enclosed.

Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed \$1,020.00 fee for a two-month extension of time and \$130.00 fee for filing a terminal disclaimer, is deemed necessary in connection with the filing of this amendment. However, if any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
<i>Gary J. Gershik</i>	4/10/07
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